

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/007092

International filing date (day/month/year)
30.06.2004

Priority date (day/month/year)
30.06.2003

International Patent Classification (IPC) or both national classification and IPC
A61K35/78, A23L1/0524, A61P3/10, A61P3/06, A23L1/0526, A23L1/053

Applicant
NESTEC S.A.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 5,6

because:

- ☒ the said international application, or the said claims Nos. 5,6 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C:-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-4 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-4 |
| Industrial applicability (IA) | Yes: Claims | 1-4 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 5 to 6 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no international preliminary examination will be made in respect of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. The documents cited in the International Search Report (ISR) are consecutively numbered D1 to D12 in the order of their listing. If not indicated otherwise, reference is made to the passages cited in said ISR.
3. With regard, to the scope of the search, a preliminary search for the subject matter of Claim 1 revealed many documents potentially relevant in respect of lack of novelty and/or inventive step of this claim. So many documents were found that a full and meaningful search of the full scope of this claim was not possible. Even a more restricted search directed towards the preferred subject matter of Claims 2 to 4 revealed many further documents potentially relevant in respect of lack of novelty and/or inventive step of this claim. Thus, the present search report merely includes a sample of the many potentially relevant documents found. A further search may be required, if and when the scope of the present claims is delimited from the presently available prior art documents. The Applicant is also warned that any delimited claims should comply with the requirements of Article 6 PCT (conciseness) and Rule 13.1/13.2 PCT (unity of invention). Further consideration will be given to this matter at the appropriate time.
4. Claim 1 defines the use of a composition comprising acetogenic fibres, *e.g.* lactulose, pectin, soybean fibre, soy fibre, acacia gum, gum arabic, tragacanth, psyllium, carob bean gum, guar gum, locust bean gum, for the preparation of a pharmaceutical composition for treating metabolic dysfunctions / conditions associated with Type 2 diabetes mellitus or insulin resistance. The wording of this claim and also the description (see also page 5 lines 27 to 30) appears to indicate that this treatment is not solely restricted to treatment of Type II diabetes/insulin

resistance but also includes treatment of conditions such as insulin resistance/dyslipidaemia, that are merely associated with Type II diabetes whether or not Type II diabetes has actually been diagnosed. This construction has been relied upon in the following assessment of lack of novelty of the claims.

5. The subject matter of Claims 1 to 4 lack novelty in view of the following prior art disclosures;

D1 and D2 disclose a nutrition intervention composition for providing glycaemic control/satiety control in Type II diabetics (see paragraph 0028 in D1 and paragraphs 0036 and 0037 in D2) comprising psyllium or pectin (see paragraph 0059 in D1 and 0062 in D2) and other fibres.

D3 discloses a composition comprising a milk protein hydrolysate further comprising acetogenic fibres such as soy, pea, pectin, guar, gum arabic and fructooligosaccharide (see paragraph 0054) for the treatment of diabetes and Syndrome X (see paragraph 0015)

D4 discloses the favourable therapeutic effects of soya and cellulose fibres of post prandial glycaemia in Type II diabetic patients.(see the conclusions)

D5 discloses guar-carob for the treatment of post prandial glycaemia in Type II diabetic patients (see the summary and the first paragraph of "Metodica dello studio" on page 498)

D6 discloses the use of locust bean gum to decrease the glycaemic index in Type II diabetic patients (see the abstract)

D7 discloses that psyllium improves glycaemic and lipid control in men with type II diabetes and hypercholesterolaemia (see the abstract)

D8 discloses the use of guar gum to treat dyslipidaemia (see title and abstract)

D9 discloses the use of guar gum (see column 1 lines 6 to 9) for improving glucose tolerance and reducing insulin requirements in Type II diabetics

D10 discloses the use of psyllium for treating dyslipidaemia (see the abstract)

D11 discloses a composition comprising pectin for reducing post prandial blood sugar levels in patients with Type II diabetes (see paragraph 0027 and Figure 3)

D12 reports an improvement in insulin sensitivity in patients treated with guar (see abstract)

6. Thus, the subject matter of Claim 1 to 4 is not new in view of the disclosures of each of documents D1 to D12 (Article 33(2) PCT).
7. It may also be helpful to note that even in the event that novelty could be established, *e.g.* by restricting the claims to particular acetogenic fibres not mentioned in the prior art, that it appears unlikely that such amended claims would fulfil the requirements of Article 33(3) PCT with respect to inventive step. In this regard, the use of dietary fibre in general to treat diabetes and dyslipidaemia appears to be well documented.